

## (Circulars)

'UTRAJEL \* \* \* CERVICAL INFECTIONS AND CERVICAL EROSIONS (Minor). \* \* \*  
 INFECTIONS OF THE CERVICAL CANAL (Minor). \* \* \*  
 'CYSTIC CERVIX. \* \* \* AS A UTERINE EVACUANT. \* \* \*  
 'UTRAJEL \* \* \* cervicitis, cervical erosions, Trichomonas vaginitis and  
 minor vaginal ulcerations \* \* \* uterine evacuant \* \* \*

and words of similar import appearing in the labeling are false and misleading since said statements represent and suggest that UtraJel is an appropriate medication for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations, and as a uterine evacuant, whereas, in truth and in fact, said drug is not an effective or appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonal vaginitis, minor vaginal ulcerations, or as a uterine evacuant.

## VIII

"Said drug is misbranded within the meaning of Section 502 (j) in that it is dangerous to health when used in the uterus in any dosage or with any frequency or with any duration of administration prescribed, recommended or suggested in its labeling.

## ORDER FOR JUDGMENT

"Upon the basis of the foregoing Findings of Fact and Conclusions of Law,  
 "It is hereby ORDERED, that a Permanent Injunction be entered accordingly, with costs against the defendants."

On January 7, 1944, a permanent injunction was entered in accordance with the court's order.

**1402. Misbranding of Grover Graham Remedy. U. S. v. S. Grover Graham Co., Inc., and Henry Wilson. Pleas of guilty. Corporate defendant fined \$250; individual defendant sentenced to 6 months' imprisonment and fined \$250. Execution of prison sentence suspended and individual defendant placed on probation for 1 year. (F. D. C. No. 12560. Sample No. 47774-F.)**

On October 23, 1944, the United States attorney for the Southern District of New York filed an information against S. Grover Graham Co., Inc., Newburgh, N. Y., and Henry Wilson, president of the corporation, alleging shipment of a quantity of the above-named product from the State of New York into the State of Missouri on or about December 21, 1943.

Analysis of samples disclosed that the article consisted essentially of sodium bromide (approximately 8.5 grains per tablespoonful), magnesia, sodium bicarbonate, alcohol, chloroform, and water flavored with oil of peppermint and colored with a red dye.

The article was alleged to be misbranded (1) because of false and misleading statements on its label which represented and suggested that it would be efficacious in the cure, mitigation, treatment, and prevention of indigestion, dyspepsia, and other ailments due to imperfect and retarded functioning of the digestive organs, and that it might be taken with perfect safety as often as necessary; (2) in that certain information required by law to appear on the label was not placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement, "Sodium Bromide U. S. P. 3½%," would not be understood by the ordinary individual and would not inform that individual of the number of grains or other measure understood by him in a tablespoonful dose; (3) in that its labeling did not bear adequate directions for use, since the directions on the label, "Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur \* \* \* Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary," provided for the consumption of an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily, whereas consumption of an excessive amount of sodium bromide might be dangerous, and limitations on the number of doses of the article to be taken daily should be contained in the directions; (4) in that its labeling failed to warn that frequent or continued use of the article might lead to mental derangement, skin eruptions, and other serious effects, and that it should not be taken by those suffering from kidney disease; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recom-

mended, and suggested in the labeling, since the directions provided for the consumption of an excessive and dangerous amount of sodium bromide.

On November 20, 1944, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of \$250 on the corporate defendant. The individual defendant was sentenced to 6 months' imprisonment and fined \$250. Execution of the prison sentence was suspended, and the individual defendant was placed on probation for 1 year.

**1403. Misbranding of Lax Laxative and Thyroid Tablets. U. S. v. 49 Envelopes of Lax Laxative and Thyroid Tablets (and 3 other seizure actions against the same product). Default decrees of condemnation and destruction.** (F. D. C. Nos. 12669, 13067, 13179, 13831. Sample Nos. 64068-F, 68126-F, 68501-F, 68502-F, 79014-F, 79019-F.)

Between June 13 and September 28, 1944, the United States attorneys for the Eastern District of Michigan, the Northern and Southern Districts of Ohio, and the Middle District of North Carolina filed libels against the following quantities of the above-named product: 49 envelopes at Detroit, Mich., 49 envelopes at New Philadelphia, Ohio, 33 envelopes at Newark, Ohio, and 31 envelopes at Greensboro, N. C.; alleging that the article had been shipped between the approximate dates of May 11 and July 12, 1944, by the Carolina Chemical Co., Charleston, S. C.

Examination disclosed that there were in each envelope a number of pink tablets which contained plant drugs, including the laxative drug aloin, and a number of white or light-colored tablets which contained approximately  $\frac{1}{2}$  grain of thyroid per tablet.

The article was alleged to be misbranded in that, by reason of the content of thyroid, it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Take one Lax Thyroid Tablet at bedtime, if you want to increase dosage you may take one before each meal \* \* \* Lax Thyroid Tablets are intended to be used as a week by week treatment. Do not expect extraordinary results from taking one packing. \* \* \* Loss of weight with Lax Thyroid Tablets does not usually start at once. It may take a few days or even a few weeks to get things started in the right direction \* \* \* It takes a little time to experience the benefits of this treatment."

The article was alleged to be misbranded further (1) in that various portions were accompanied by a circular entitled "Lax Thyroid Tablets," which contained false and misleading representations that the article was a safe and effective remedy for obesity, and that it would produce greater vitality and a general feeling of well-being; and (2) in that portions of the article failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of the contents, or the common or usual name of each active ingredient and the name and quantity of thyroid contained in the article.

Between August 7 and December 12, 1944, no claimant having appeared, judgments were entered condemning the product and ordering its destruction.

**1404. Misbranding of White's Cream Vermifuge. U. S. v. 32 Dozen Packages of White's Cream Vermifuge. Default decree of condemnation and destruction.** (F. D. C. No. 12747. Sample No. 80008-F.)

On June 23, 1944, the United States attorney for the Western District of Tennessee filed a libel against 32 dozen packages of White's Cream Vermifuge at Memphis, Tenn., alleging that the article had been shipped on or about March 15, 1944, by James F. Ballard, Inc., from St. Louis, Mo.

Analysis of a sample disclosed that the article consisted essentially of oil of Chenopodium 3.1 percent, castor oil, and a small amount of peppermint oil.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling: (On carton and bottle label) "Dose: Children 3 to 5 years of age, half teaspoonful; \* \* \* One dose morning and night for 2 or 3 days"; and (on circular in carton) "For children 3 to 5 years of age  $\frac{1}{2}$  teaspoonful. \* \* \* The regular dose should be given morning and evening, after meals, for 2 or 3 days." The labeling provided for an amount of oil of Chenopodium that is dangerous to the health of children 3 to 5 years of age.

The article was alleged to be misbranded further in that the following statements in the circular entitled "White's Cream Vermifuge," enclosed in the carton containing the article, were misleading: "There are numerous symptoms that indicate the presence of worms in children. Infestation of Round Worms in a child often affects the child's sleep, appetite, and well-being. At the first recogni-